

Appl. No. 09/834,307

Amendment dated April 15, 2004

Reply to Office Action of January 15, 2004

CONFIDENTIAL DRAFT

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

Claim 23 (previously presented): A medicated device comprising:

a scaffold comprising adjacent edges or surfaces in close proximity to each other; and

a coating on said scaffold, said coating being on said surfaces and bridging from one edge or surface to another, and said coating comprising at least one polymer and at least one therapeutic agent,

said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 24 (previously presented): The medicated device of claim 23, said therapeutic agent being at a loading of at least about 500 micrograms per square centimeter of coating.

Claim 25 (previously presented): The medicated device of claim 23, said coating comprising a bond coat layer and a layer comprising the pharmaceutical agent.

Claim 26 (previously presented): The medicated device of claim 23, said scaffold comprising a wire configured into a coil.

Claim 27 (previously presented): The medicated device of claim 26, said scaffold comprising a wire configured into a coil having open windings.

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Claim 28 (previously presented): The medicated device of claim 23, said scaffold selected from the group consisting of perforated wafers and wire meshes.

Claim 29 (currently amended): The medicated device of claim 23, said scaffold selected from the group consisting of mandrels, beads, cylinders, egg-shaped articles, spheres, coiled articles, straight articles, threads, wires, pellets, tubing, and stents configured to have adjacent edges or surfaces in close proximity to each other.

Claim 30 (previously presented): The medicated device of claim 23, wherein when said device is implanted in a tissue, therapeutic amounts of said therapeutic agent diffuses at least about one centimeter from said device.

Claim 31 (previously presented): The medicated device of claim 23, wherein in a zone of inhibition test, effective amounts of the therapeutic agent diffuse at least about one half centimeter from said device.

Claim 32 (previously presented): The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of an antibiotic agent, an anticancer agent, an antiangiogenic agent, an antimicrobial agent, an antiviral agent, and an antithrombogenic agent.

Claim 33 (currently amended): The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of taxotere, fluorouracil, doxarubicin, cisplatin, mitomycin, peplomycin, merbarone, minocycline, penicillins, cephalosporins, fluoroquinolones, tetracyclines, Chloramphenicol, Polymixin B sulfate, Bacitracin zinc, aminoglycosides, ~~clindamycin~~, clindamycin, lincomycin, thymol, silver compounds, polyhexamethylenebeguanide hydrochloride, benzethonium chloride, stearalkonium chloride, ~~1,2-benzisothiazolin-3-one~~, 1,2-benzisothiazolin-3-

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one, triclosan, vantacil, vantocil, heparin sodium, heparin complexed with a quaternary ammonium compound, heparin complexed with benzalkonium chloride, stearalkonium chloride, tridodecylmethylammonium chloride, hirudin, sugars, and aspirin.

Claim 34 (previously presented): The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of rifamycin, gentamicin laurylsulfate, VANTOCIL® IB, benzalkonium chloride, BRONOPOL-BOOTS® BP, silver nitrate, methotrexate, and paclitaxel.

Claim 35 (currently amended): The medicated device of claim 32 23, said therapeutic agent comprising heparin and at least one additional agent.

Claim 36 (previously presented): The medicated device of claim 23, said coating comprising at least one hydrophobic polymer and at least one hydrophilic polymer.

Claim 37 (previously presented): The medicated device of claim 23, said coating comprising a first polymer and a second polymer, said first polymer more hydrophilic than said second polymer.

Claim 38 (previously presented): The medicated device of claim 36, said hydrophilic polymer comprising a polymer being one or more selected from the group consisting of a polyacrylamide/ethylene glycol copolymer, and a polyacrylamide/polyethylene oxide copolymer, polyvinylpyrrolidone, polyvinylpyrrolidone vinylacetate copolymer, a polyethylene glycol, and a polyethylene oxide.

Claim 39 (previously presented): The medicated device of claim 36, said hydrophobic polymer comprising an acrylate/carboxyl copolymer, a cellulose ester polymer, cellulose nitrate, a polyurethane polymer, an acrylate polymer, and an acrylate copolymer.

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Claim 40 (previously presented): The medicated device of claim 36, said coating comprising at least as much hydrophobic polymer as hydrophilic polymer by weight.

Claim 41 (previously presented): The medicated device of claim 36, said coating comprising hydrophobic polymer and hydrophilic polymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 42 (previously presented): The medicated device of claim 23, said coating comprising an acrylate polymer and polyvinylpyrrolidone/vinyl acetate copolymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 43 (previously presented): A method for making a medicated device, comprising the steps of:

providing a scaffold comprising edges or surfaces in close proximity to each other;

providing a coating material comprising at least one polymer and at least one therapeutic agent; and,

applying the coating material to said scaffold to produce a coating on said surfaces of said scaffold and bridging from one edge or surface to another, said therapeutic agent being in the coating at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 44 (previously presented): The method of claim 43, ~~said applying~~ comprising applying a polymeric coating sheath to said scaffold, and applying to said sheath a coating layer comprising said polymer and said therapeutic agent.

Claim 45 (previously presented): A method of providing a therapeutic agent to a target tissue, comprising the steps of:

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providing a medicated device comprising a scaffold comprising adjacent edges or surfaces in close proximity to each other, a coating on said scaffold, said coating being on said surfaces and bridging from one edge or surface to another, and said coating containing at least one polymer and at least one therapeutic agent and comprising one or more layers, said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of coating; and,

inserting the medicated device into the target tissue to provide therapeutic benefit, wherein

a therapeutic amount of said therapeutic agent diffuses into the tissue at least about one centimeter from said device.

Claim 46 (previously presented): The method of claim 45, the tissue comprising a tumor or a lesion.

Claim 47 (previously presented): The method of claim 45, said inserting comprising inserting the medicated device into a tumor, wherein said therapeutic agent comprises an anti-cancer drug.

Claim 48 (previously presented): The method of claim 45, said inserting comprising inserting the medicated device into a lesion, wherein said therapeutic agent comprises an antibiotic.

Claim 49 (previously presented): The method of claim 45, further comprising inserting the medicated device using a trochar or catheter.

Claim 50 (new): A medicated device comprising:

a substrate suitable for implantation into a patient's body comprising adjacent edges or surfaces in close proximity to each other; and

a formulation comprising at least one polymer and at least one therapeutic agent, the formulation bridging from one edge or surface to another,

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said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of the device.

Claim 51 (new): The device of claim 50 wherein the substrate has an open, perforated, or mesh structure providing support for the formulation.

Claim 52 (new): The device of claim 50 wherein the substrate is a stent.

Claim 53 (new): The device of claim 50 wherein the therapeutic agent comprises paclitaxel.

Claim 54 (new): The device of claim 50 wherein the substrate is a stent and the therapeutic agent comprises paclitaxel.

Claim 55 (new): The device of claim 54 wherein the stent elutes about 10% of the paclitaxel over about 14 days.